

Exhibit H



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Catherine V Beath
ETHICON INC.
Route 22 West, PO Box 151
Somerville, NJ 08876

JAN 03 2012

Re: Postmarket Surveillance (PS) Study: PS120095
Trade Name: GYNECARE TVT SECUR SYSTEM
510(K) Number: K052401

Dear Catherine V Beath:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) notified you by letter, dated November 28, 2005, that the GYNECARE TVT SECUR SYSTEM was cleared under premarket notification (510(k)) K052401.

Section 522 of the Federal Food, Drug, and Cosmetic Act (the act), 21 U.S.C. 360l, authorizes FDA to require a manufacturer to conduct postmarket surveillance of a class II or class III device that meets any of the following criteria: (1) its failure would be reasonably likely to have serious adverse health consequences; (2) it is expected to have significant use in pediatric populations; (3) it is intended to be implanted in the body for more than one year; or (4) it is intended to be a life-sustaining or life-supporting device used outside a device user facility.

Your device is subject to postmarket surveillance under section 522 because it is a class II device that meets two of these criteria. Its failure would be reasonably likely to cause mesh erosion (i.e. organ perforation), severe pain, and fistula formation, which would meet the definition of "serious adverse health consequences" at 21 C.F.R. § 822.3(j). In addition, since your device is a permanent implant, it is intended to be implanted in the body for more than one year.

When FDA orders postmarket surveillance, the manufacturer must submit a plan to conduct the surveillance. FDA will then determine whether the plan will result in the collection of useful data that can reveal unforeseen adverse events or other information necessary to protect the public health. Here, FDA is concerned with potential safety risks as evidenced by adverse events reported to the FDA. In addition, FDA is concerned with published literature indicating lack of added clinical benefit without reduced rates of repeat surgery compared to multi-incision retropubic or transobturator mesh slings.

Accordingly, under section 522 of the act, we are ordering you to conduct a postmarket surveillance study of your device to address our questions below.

1. Among all women undergoing stress urinary incontinence surgery, what proportion is exposed to this device and what type of surgical procedures are performed?

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1. Is the rate of effectiveness with use of this device non-inferior to the rate seen in patients with a comparator multi-incision retropubic or transobturator mesh sling?
 - a. Among women exposed to your device for stress urinary incontinence surgery, what effectiveness is observed within 6 months, 12 months, 18 months, 24 months, and 36 months?
 - b. What is the rate of effectiveness noted with use of this device within 6 months, 12 months, 18 months, 24 months, and 36 months?
2. What are the rates associated with each of the following adverse events through 36 months post-implant: organ perforation, bleeding (including hemorrhage and hematoma), mesh exposure in the vagina, mesh erosion into the bladder, pelvic pain, infection, de novo dyspareunia, urinary retention, recurrent incontinence, other urinary problems, neuromuscular problems, revision/resurgery?
 - a. Are the rates of adverse events associated with use of this device non-inferior to the rates seen in patients with a comparator multi-incision retropubic or transobturator mesh sling?
 - b. Are the rates of revision/resurgery associated with use of this device non-inferior to the rates seen in patients who are exposed to a comparator multi-incision retropubic or transobturator mesh sling?
 - c. Among women exposed to your device for stress urinary incontinence surgery, what adverse events are observed within 6 months, 12 months, 18 months, 24 months, and 36 months?
 - d. What is the overall rate of adverse events noted with use of this device within 6 months, 12 months, 18 months, 24 months, and 36 months?
 - e. For mesh exposure and erosion, what are the rates and severity of events observed within 6 months, 12 months, 18 months, 24 months, and 36 months?
3. What is the quality of life for women who have received this device at 6 months, 12 months, 18 months, 24 months, and 36 months post-surgery? Does the quality of life among women who have had stress urinary incontinence surgery with this device differ from those who have had similar surgeries with use of a comparator multi-incision retropubic or transobturator mesh sling?
4. Among patients with resurgery within 36 months after initial stress urinary incontinence surgery with this mesh:
 - a. what are the rates of adverse events and what is the quality of life during the period after resurgery?
 - b. do the rates of adverse events after resurgery differ between patients whose initial stress urinary incontinence surgery included this mesh compared with those using a comparator multi-incision retropubic or transobturator mesh sling?

Within 30 days of receipt of this order, you must submit your plan to conduct postmarket surveillance of your device to the address listed below. Your submission should clearly identify it as a postmarket surveillance plan and include the PS number referenced above.

You should send three (3) copies of your plan to:

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Mary Beth Ritchey, PhD
Food and Drug Administration
10903 New Hampshire Ave
WO66-4118
Silver Spring, MD 20993-0002

To address the issues cited above, FDA recommends a randomized clinical trial (RCT) or prospective cohort study design that compares your device(s) to a control (i.e., multi-incision retropubic or transobturator mesh sling) based upon the design and orientation (i.e. "U" or hammock style) of mesh placement through 3 years of follow-up. Depending on the study design that you propose and justify, you may choose to work with sponsors of other surgical meshes indicated for treatment of stress urinary incontinence. If you believe that you have existing data to justify an alternative study design, such as a retrospective cohort study, FDA suggests you first contact us to discuss the extent of the data and its adequacy to address public health issues #2 - #5 above.

FDA recommends testing effectiveness of the device via urodynamic testing, post-void residual volume, frequency as reported by the patient or 3-day pad weight test as discussed in the Guidance for Industry and Food and Drug Administration Staff: Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence (<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070854.pdf>).

In lieu of one of the study designs recommended above, you may choose to develop a new sponsor registry or RCT/cohort study nested within a registry to address these public health questions, either as a single institution or in collaboration with other sponsors. FDA is amenable to facilitating creation of a multi-sponsor registry to address these public health questions. If you choose to address these questions through a multi-sponsor registry, please contact FDA within 15 days of receipt of this order.

FDA recommends a study design including a population of women who are age 18 years or older with documented stress urinary incontinence diagnosis for whom surgery is scheduled. FDA suggests inclusion and adjustment for the following risk factors: menopausal status; estrogen use; age; smoking; diagnosis of diabetes; body mass index; hysterectomy status; concomitant procedures; surgeon training and experience with this mesh (e.g. number of years performing procedure or volume of procedures performed in past 12 months). FDA recommends specifying the direction of placement of the comparator device. In addition, FDA recommends use of validated instrument(s) for quality of life measures (e.g. Pelvic Floor Impact Questionnaire (PFIQ)). For question 3, FDA recommends classifying "severity" of mesh exposure and erosion based on need for one of the following four types of intervention: none or medical intervention only, minor or intra-office surgical intervention, outpatient surgery, inpatient surgery.

The clinical experience gathered from your postmarket surveillance study may lead FDA to, among other things, recommend labeling changes regarding the use of your devices.

Failure of a manufacturer to meet its obligations under section 522 is a prohibited act under section 301(q)(1)(C) of the act, 21 U.S.C. 331(q)(1)(C). Further, under section 502(t)(3) of the act, 21 U.S.C. 352(t)(3), a device is misbranded if there is a failure or refusal to comply with any requirement under section 522 of the act. Please note that violations of sections 301(q)(1)(C) or

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502(t)(3) may lead to regulatory actions including seizure of your product, injunction, prosecution, or civil money penalties.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Thomas Gross', is written over the printed name.

Thomas Gross, MD, MPH

Acting Director

Office of Surveillance and Biometrics

Center for Devices and Radiological Health

Food and Drug Administration